

REMARKS

Claims 1-11 and 16 are pending. No new matter has been added by way of the present amendment. For instance, the recitation of language relating to "partial" peptide sequences have been removed from the claims. Additionally, the "prevention" language has been removed from claims 6, 8 and 9. Lastly, an inadvertent typographical error in claim 4 has been corrected. Accordingly, no new matter has been added.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 USC § 112, first paragraph (enablement)

The Examiner has rejected claims 1-11 and 16 under 35 USC § 112, first paragraph for the reasons recited at pages 2-5 of the outstanding Office Action. Applicants respectfully traverse. In essence, the Examiner has maintained the previous rejection of claims 1-10 (including newly added claim 16) under 35 U.S.C. § 112, first paragraph. However, the Examiner's rejection now relates only to enablement and not written description.

First, the Examiner asserts that sufficient enablement does not exist for all of the types of "partial sequences" encompassed

by the present claims. Applicants traverse and submit that all language relating to "partial sequences" has been removed from the claims. Accordingly, this aspect of the rejection is moot. Reconsideration and withdrawal thereof are requested.

Second, the Examiner asserts that there is insufficient enablement for "prevention" of the various diseases in claims 6-9 and 16. Applicants traverse and submit that the language relating to "prevention" of these diseases has been removed from the claims. Accordingly, this aspect of the rejection is moot. Reconsideration and withdrawal thereof are requested.

Third, the Examiner asserts that there is insufficient disclosure in the specification to correlate the *in vitro* data with *in vivo* success. Applicants respectfully disagree with the Examiner. In fact, Applicants submit that the *in vitro* data can be correlated to *in vivo* efficacy.

Applicants submit that the references relied upon by the Examiner (wherein a correlation between the *in vitro* data and *in vivo* data is allegedly negated) are exceptional cases. Contrary to these references, Applicants submit that once efficacy of a certain chemical compound is proven *in vitro*, the corresponding efficacy *in vivo* can be demonstrated with a high probability.

In connection with this issue, Applicants attach a copy of each of U.S. Patent Nos. 5,646,148, 5,807,841, and 6,417,191. These U.S. Patents are illustrative of the situations wherein the invention of a method or pharmaceutical formulation of treating or preventing HIV infection has been patented. In these instances, there is the demonstration of *in vitro* data alone using cell lines, but no demonstration of *in vivo* clinical data. As such, Applicants submit that sufficient enablement exists for such claims, even without *in vivo* data. Thus, these patents are illustrative of the fact that the *in vitro* data is normally correlated to *in vivo* efficacy, even without disclosure of such *in vivo* data. In contrast, the references cited by the Examiner are exceptional cases of no relevance to the present invention.

In view of the above, Applicants respectfully submit that the present claims are fully enabled. Reconsideration and withdrawal of the outstanding rejections are respectfully requested.

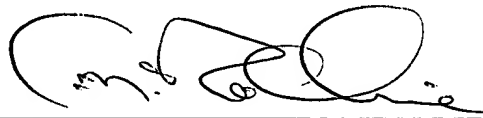
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc Weiner (Reg. No. 32,181) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), Applicant hereby petitions for an extension of three (3) months to April 9, 2004 in which to file a reply to the Office Action. The required fee of \$950.00 is enclosed herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
Marc Weiner, #32,181

Craig A. McRobbie, #42,874

MSW/CAM/mmi/bsh
0020-4867P

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

Attachment: Copies of U.S. Patent Nos. 5,646,148, 5,807,841, and
6,417,191